

**MULTIVITAMIN WITH FLUORIDE- vitamin a acetate, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, and sodium fluoride tablet, chewable  
H2-Pharma, LLC**

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**MultiVitamin  
with Fluoride  
Chewable Tablets**

**DOSAGE AND ADMINISTRATION**

One tablet daily or as directed by a physician.

<b>Supplement Facts</b>		
<b>Serving Size 1 Tablet</b>		
<b>Servings Per Container 100</b>		
	<b>Amount Per Serving</b>	<b>% Daily Value</b>
Vitamin A	750 mcg (2500 IU)	83%
Vitamin C	60 mg	67%
Vitamin D	10 mcg (400 IU)	50%
Vitamin E	6.75 mg (15 IU)	45%
Thiamine	1.05 mg	88%
Riboflavin	1.2 mg	92%
Niacinamide	13.5 mg	84%
Vitamin B <sub>6</sub>	1.05 mg	62%
Folate (Folic Acid)	500 mcg DFE (0.3 mg)	125%
Vitamin B <sub>12</sub>	4.5 mcg	188%
Fluoride	0.25 mg	*

\* Daily Value not established

**WARNING**

**KEEP OUT OF THE REACH OF CHILDREN.**

In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Other Ingredients: ascorbic acid, cholecalciferol, compressible sugar, cyanocobalamin, dl-alpha-tocopheryl acetate, FD&C Yellow #6 aluminum lake, folic acid, magnesium stearate, microcrystalline cellulose, natural and artificial orange flavor, niacinamide, polyethylene glycol, pyridoxine HCl, riboflavin, sodium ascorbate, sodium fluoride, stearic acid, sucralose, thiamine mononitrate and vitamin A acetate.

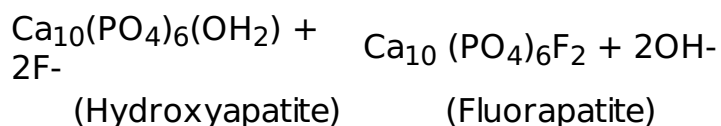
**Active ingredient for caries prophylaxis:** Fluoride as sodium fluoride.

## CLINICAL PHARMACOLOGY

Significant decrease in the incidence of dental caries can be linked to the fluoridation of the water supply (1ppm fluoride) during the period of tooth development.

**MultiVitamin with Fluoride Chewable Tablets** provide sodium fluoride and ten essential vitamins in a chewable tablet. Because the tablets are chewable, they provide a topical as well as systemic source of fluoride. Hydroxyapatite is the principal crystal for all calcified tissue in the human body. The fluoride ion reacts with the hydroxyapatite in the tooth as it is formed to produce the more caries-resistant crystal fluorapatite.

The reaction may be expressed by the equation:



Three stages of fluoride deposition in tooth enamel can be distinguished:

1. Small amounts (reflecting the low levels of fluoride in tissue fluids) are incorporated into the enamel crystals while they are being formed.
2. After enamel has been laid down, fluoride deposition continues in the surface enamel. Diffusion of fluoride from the surface inward is apparently restricted.
3. After eruption, the surface enamel acquires fluoride from the water, food, supplementary fluoride and smaller amounts of saliva.

## DIETARY SUPPLEMENTATION

MultiVitamins with Fluoride Chewable Tablets offer supplementation of the diet with 10 vitamins and fluoride.

## WARNINGS

**AS IN THE CASE OF ALL MEDICATIONS, KEEP OUT OF THE REACH OF CHILDREN.** This tablet should be chewed. This product, as with all chewable tablets, are not recommended for children under the age of 4 due to risk of choking.

## PRECAUTIONS

The suggested dose of **MultiVitamin with Fluoride Chewable Tablets** should not be exceeded, since dental fluorosis may result from continued ingestion of large amounts of fluoride.

Before recommending **MultiVitamin with Fluoride Chewable Tablets**

1. Determine the fluoride content of the drinking water from all major sources.
2. Make sure the child is not receiving significant amounts of fluoride from other sources such as medications and swallowed toothpaste.

3. Periodically check to make sure that the child does not develop significant dental fluorosis.

## **ADVERSE REACTIONS**

Allergic rash and other idiosyncrasies have been rarely reported.

**To report SUSPECTED ADVERSE REACTIONS, contact H2-Pharma, LLC at 1 (866) 592-6438 or FDA at 1 (800) 332-1088 or via the web at [www.fda.gov/medwatch/index.html](http://www.fda.gov/medwatch/index.html) for voluntary reporting of adverse reactions.**

## **DOSAGE AND ADMINISTRATION**

One tablet daily or as directed by a physician.

## **HOW SUPPLIED**

**MultiVitamin with Fluoride Chewable Tablets** 0.25 mg are available as orange chewable tablets imprinted with "155" in 100 tablet bottles.

**MultiVitamin with Fluoride Chewable Tablets** 0.5 mg are available as orange chewable tablets imprinted with "156" in 100 tablet bottles.

**MultiVitamin with Fluoride Chewable Tablets** 1.0 mg are available as orange chewable tablets imprinted with "157" in 100 tablet bottles.

## **STORAGE**

Store at controlled room temperature 20°C-25°C (68°-77°F), excursions permitted between 15°-30°C (59°-86°F) [See USP].

Tamper Evident

Do not use if seal under cap is torn, broken or missing.

Distributed by:

**H2-Pharma, LLC**

Montgomery, AL 36117

## **PRINCIPAL DISPLAY PANEL - 0.25 mg Tablet Bottle Label**

61269-155-01

MultiVitamin  
with Fluoride  
Chewable Tablets

0.25 mg

MultiVitamin and Fluoride Supplement

Dietary Supplement

Orange Flavor

100 Tablets

H<sup>2</sup> pharma

Distributed by:  
**H2-Pharma, LLC**  
Montgomery, AL 36117  
www.h2-pharma.com

61269-155-01

# MultiVitamin

with Fluoride  
Chewable Tablets

**0.25 mg**  
**MultiVitamin and Fluoride Supplement**  
Dietary Supplement  
Orange Flavor

100 Tablets



**DOSAGE AND ADMINISTRATION:**  
One tablet daily or as directed by a physician.

### Supplement Facts

Serving Size 1 Tablet  
Servings Per Container 100

	Amount Per Serving	% Daily Value
Vitamin A	750 mcg (2500 IU)	63%
Vitamin C	60 mg	67%
Vitamin D	10 mcg (400 IU)	50%
Vitamin E	6.75 mg (15 IU)	45%
Thiamine	1.05 mg	88%
Riboflavin	1.2 mg	92%
Niacinamide	13.5 mg	84%
Vitamin B <sub>6</sub>	1.05 mg	62%
Folate (Folic Acid)	500 mcg DFE (0.3 mg)	125%
Vitamin B <sub>12</sub>	4.5 mcg	188%
Fluoride	0.25 mg	*

\*Daily Value not established

**WARNING: KEEP OUT OF THE REACH OF CHILDREN.**

In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Other Ingredients: ascorbic acid, cholecalciferol, compressible sugar, cyanocobalamin, di-alpha-tocopheryl acetate, FD&C Yellow #6 aluminum lake, folic acid, magnesium stearate, microcrystalline cellulose, natural and artificial orange flavor, niacinamide, polyethylene glycol, pyridoxine HCl, riboflavin, sodium ascorbate, sodium fluoride, stearic acid, sucralose, thiamine mononitrate and vitamin A acetate.

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## PRINCIPAL DISPLAY PANEL - 0.5 mg Tablet Bottle Label

61269-156-01

MultiVitamin  
with Fluoride  
Chewable Tablets

0.5 mg

MultiVitamin and Fluoride Supplement

Dietary Supplement  
Orange Flavor

100 Tablets

H<sup>2</sup> pharma

Distributed by:  
**H2-Pharma, LLC**  
Montgomery, AL 36117  
www.h2-pharma.com

61269-156-01

# MultiVitamin

with Fluoride  
Chewable Tablets

**0.5 mg**  
MultiVitamin and Fluoride Supplement

Dietary Supplement  
Orange Flavor

100 Tablets



**DOSAGE AND ADMINISTRATION:**  
One tablet daily or as directed by a physician.

### Supplement Facts

Serving Size 1 Tablet  
Servings Per Container 100

	Amount Per Serving	% Daily Value
Vitamin A	750 mcg (2500 IU)	83%
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Folate (Folic Acid)	500 mcg DFE (0.3 mg)	125%
Vitamin B <sub>12</sub>	4.5 mcg	188%
Fluoride	0.5 mg	*

\*Daily Value not established

**WARNING: KEEP OUT OF THE REACH OF CHILDREN.**  
In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Other Ingredients: ascorbic acid, cholecalciferol, compressible sugar, cyanocobalamin, di-alpha-tocopheryl acetate, FD&C Yellow #6 aluminum lake, folic acid, magnesium stearate, microcrystalline cellulose, natural and artificial orange flavor, niacinamide, polyethylene glycol, pyridoxine HCl, riboflavin, sodium ascorbate, sodium fluoride, stearic acid, sucralose, thiamine mononitrate and vitamin A acetate.

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## PRINCIPAL DISPLAY PANEL - 1 mg Tablet Bottle Label

61269-157-01

MultiVitamin  
with Fluoride  
Chewable Tablets

1 mg

MultiVitamin and Fluoride Supplement

Dietary Supplement  
Orange Flavor

100 Tablets

H<sup>2</sup> pharma

Distributed by:  
**H2-Pharma, LLC**  
Montgomery, AL 36117  
www.h2-pharma.com

61269-157-01

# MultiVitamin

with Fluoride  
Chewable Tablets

**1 mg**  
MultiVitamin and Fluoride Supplement

Dietary Supplement  
Orange Flavor

100 Tablets



**DOSAGE AND ADMINISTRATION:**  
One tablet daily or as directed by a physician.

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Servings Per Container 100

	Amount Per Serving	% Daily Value
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Vitamin B <sub>12</sub>	4.5 mcg	188%
Fluoride	1 mg	*

\*Daily Value not established

**WARNING: KEEP OUT OF THE REACH OF CHILDREN.**  
In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Other Ingredients: ascorbic acid, cholecalciferol, compressible sugar, cyanocobalamin, di-alpha-tocopheryl acetate, FD&C Yellow #6 aluminum lake, folic acid, magnesium stearate, microcrystalline cellulose, natural and artificial orange flavor, niacinamide, polyethylene glycol, pyridoxine HCl, riboflavin, sodium ascorbate, sodium fluoride, stearic acid, sucralose, thiamine mononitrate and vitamin A acetate.

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**MULTIVITAMIN WITH FLUORIDE**

vitamin a acetate, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, and sodium fluoride tablet, chewable

## Product Information

<b>Product Type</b>	DIETARY SUPPLEMENT	<b>Item Code (Source)</b>	NHRIC:61269-155
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>VITAMIN A ACETATE</b> (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	750 ug
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	60 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	6.75 mg
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.05 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.2 mg
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	13.5 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	1.05 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	500 ug
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	4.5 ug
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.25 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SODIUM ASCORBATE</b> (UNII: S033EH8359)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:61269-155-01	100 in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Dietary Supplement		11/01/2022	

## Supplement Facts

Serving Size :

Serving per Container :

	Amount Per Serving	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	13 mm	
imprint		
flavor		

## MULTIVITAMIN WITH FLUORIDE

vitamin a acetate, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, and sodium fluoride tablet, chewable

### Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:61269-156
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>VITAMIN A ACETATE</b> (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	750 ug
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	60 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	6.75 mg
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.05 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.2 mg
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	13.5 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	1.05 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	500 ug
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	4.5 ug
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	

<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SODIUM ASCORBATE</b> (UNII: S033EH8359)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:61269-156-01	100 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Dietary Supplement		11/01/2022	

### Supplement Facts

**Serving Size :** \_\_\_\_\_ **Serving per Container :** \_\_\_\_\_

	Amount Per Serving	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	13 mm	
imprint		
flavor		

### MULTIVITAMIN WITH FLUORIDE

vitamin a acetate, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, and sodium fluoride tablet, chewable

#### Product Information

<b>Product Type</b>	DIETARY SUPPLEMENT	<b>Item Code (Source)</b>	NHRIC:61269-157
<b>Route of Administration</b>	ORAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>VITAMIN A ACETATE</b> (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	750 ug
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	60 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8) (.ALPHA.-	.ALPHA.-TOCOPHEROL,	6.75 mg



TOCOPHEROL, DL- - UNII:7QWA1RIO01)	DL-	0.75 mg
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.05 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.2 mg
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	13.5 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	1.05 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	500 ug
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	4.5 ug
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	1 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SODIUM ASCORBATE</b> (UNII: S033EH8359)	
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### Supplement Facts

Serving Size :

Serving per Container :

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color		
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size (solid drugs)	13 mm	
imprint		
flavor		

**Labeler** - H2-Pharma, LLC (028473634)

